

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

<p>ALAN DALEWITZ, on behalf of himself and all others similarly situated,</p> <p style="text-align:center">Plaintiff,</p> <p style="text-align:center">v.</p> <p>THE PROCTER & GAMBLE COMPANY,</p> <p style="text-align:center">Defendant.</p>	<p>Case No. 7:22-cv-07323</p> <p>The Honorable Nelson S. Román</p>
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**REPLY MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR
LEAVE TO FILE A SECOND AMENDED COMPLAINT**

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INTRODUCTION

While Defendant the Procter & Gamble Company (“P&G” or “Defendant”) may have predicted this Court’s dismissal of Plaintiff Dalewitz’s (“Plaintiff”) initial complaint due to Plaintiff’s reliance upon Total Organic Fluorine (“TOF”) testing, that is where Defendant’s accuracy ends with respect to its opposition to Plaintiff’s request for leave to file a Second Amended Complaint (“SAC”). The law on whether TOF testing is adequate to allege the presence of per-and- polyfluorinated substances (“PFAS”) remains unsettled and is highly dependent upon the facts of the particular product at issue. Defendant’s counsel forgets that they are neither judge nor jury, and that “told you so” is never a convincing legal argument.

Further, contrary to Defendant’s assertions, Plaintiff has not missed a single deadline in this action, but instead, properly sought and received an extension from this Court before timely filing the First Amended Complaint, and now timely moves this Court for leave to file a Second Amended Complaint (after Defendant refused consent) based upon the very test results that this Court determined were necessary to support Plaintiff’s claims. Plaintiff’s recent results reveal that specific PFAS with known, harmful health and environmental effects are present in Oral-B Glide Dental Floss (the “Product”) which Defendant markets as “Pro-Health” and sustainable. Unfortunately, Plaintiff did not receive the results in time to include them in the First Amended Complaint due to delays at the laboratory, but promptly moved for leave to file the SAC while this case remains at the pleading stage.

This is a putative class action on behalf of consumers who have purchased the Product, which is emblazoned with the term “Pro-Health” along with related safety and sustainability representations touted on Defendant’s consumer-facing website. PFAS are synthetic chemicals known to bioaccumulate in the human body and the environment and are one of the most mobile

classes of chemicals. Defendant's conduct in leading consumers to believe that Oral-B Glide dental floss is safe and "healthy" is particularly egregious considering the intended use for the Product, i.e., the PFAS-laden Product makes direct contact with consumers' mouth, teeth and gums, migrating into the user's body via oral absorption or ingestion and contributing to the consumer's overall body burden of PFAS. By marketing its toxic Product as "Pro-Health" and sustainable, Defendant is preying upon conscious consumers, like Plaintiff, who strive to make healthier choices, only to then be secretly exposed by Defendant to these harmful chemicals. Defendant should be held accountable for its deception and profound indifference to the well-being of consumers who fall victim to Defendant's health claims. Plaintiff respectfully requests that this Court consider his recent test results which unequivocally demonstrate that the Product contains harmful PFAS, by allowing Plaintiff to file the Second Amended Complaint and to have his case heard on the merits. Defendant's arguments in opposition to Plaintiff's request are unavailing for the reasons explained herein.

ARGUMENT

I. DEFENDANT'S OPPOSITION MISCHARACTERIZES CASE LAW RELATING TO TOTAL ORGANIC FLUORINE TESTING.

P&G attempts to paint Plaintiff's initial Complaint as unreasonable due to the dismissal of a handful of other cases which alleged the presence of PFAS in consumer products without a direct PFAS test. However, legal precedent on this issue is far from settled, a fact that is only further demonstrated by the cases cited in Defendant's Opposition. For example, in *Andrews v. The Procter & Gamble Co.*, plaintiff did not perform any independent testing (neither total organic fluorine ("TOF") nor direct) No. EDCV 19-00075 AG (SHKx), 2019 U.S. Dist. LEXIS 211567 (C.D. Cal. June 3, 2019), but instead relied upon reported third-party test results that revealed the

presence of fluorine (as opposed to organic fluorine, the test initially relied upon by Plaintiff here, and a more reliable indicator of PFAS).

A TOF test presents a scientifically valid method of testing for PFAS used by researchers, regulators, and legislatures. Courts have acknowledged that fluorine testing is an appropriate measure for testing for the presence of PFAS. In fact, the United States District Court for the Southern District of California held that a consumer plaintiff's claims that defendant's packaging contained "heightened levels of organic fluorine," a marker of PFAS, is "plausible because Plaintiffs allege that based on the Consumer Reports article, similar studies and reports, and their own tests, the Products are likely to contain PFAS and that PFAS are dangerous even in small quantities." *Hamman, et al., v. Cava Grp., Inc.*, No. 22-cv-593-MMA (MSB), 2023 U.S. Dist. LEXIS 85634, at *12 (S.D. Cal. Feb. 8, 2023) (internal citations omitted). *GMO Free USA v. Cover Girl Cosmetics*, No. 2021 CA 004786 B, slip op. (D.C. Super. Ct. June 1, 2022) is easily distinguishable as the product at issue disclosed the inclusion of PTFE ***on the product package***, and the court in that case found that plaintiff "plausibly allege[d] that the product contains PFAS based on its fluorine testing."

Defendant cannot truly be suggesting that it was somehow improper for Plaintiff to file his initial claims supported by TOF testing based upon a single, nonbinding decision from D.C. Superior Court? (*GMO Free USA v. Procter & Gamble Co.*, No. 2022 CA 4128 B, slip op. (D.C. Super. Ct. July 3, 2023).) As explained above, legal precedent regarding the requisite type of test to support PFAS allegations was far from settled when the Complaint was filed and the Order was issued. Plaintiff has now been able to indisputably confirm that the TOF results were correct, and that the Product does in fact contain PFAS. Plaintiff simply seeks to amend its complaint accordingly.

II. RULE 15(A) APPLIES, AND PLAINTIFF HAS DEMONSTRATED THAT THIS COURT SHOULD PERMIT AMENDMENT IN THE INTEREST OF JUSTICE.

Defendant's strained argument that this Court's Individual Practice Rule 1(E) applies in place of FRCP 15(a) is a transparent and fundamentally flawed attempt to convince this Court to impose a heightened "extraordinary circumstances" standard in place of the proper, more deferential standard of FRCP 15(a). Even if Individual Practice Rule 1(E) applies in the context of motion practice, Plaintiff has diligently sought extensions and complied with every court-ordered deadline in this case. Furthermore, this Court expressly permitted Plaintiff to file this motion seeking leave to file the SAC by Order dated March 6, 2024. (ECF No. 23).

Contrary to Defendant's assertion that Plaintiff "missed the deadline" to amend his complaint, Plaintiff in fact sought (and thereafter received) this Court's permission for an extension prior to the deadline set forth in this Court's September 22, 2023 Order of dismissal (the "Order") on October 17, 2023. (*See* ECF No. 16). In Plaintiff's October 17, 2023 letter to the Court, Plaintiff's counsel requested a 60 day extension for time to perform "additional investigation and testing" before being required to file an amended complaint. On October 20, 2023, this Court granted Plaintiff's request for an extension, but only through November 13, 2023. (ECF No. 16). As such, on November 13, 2023, Plaintiff filed his First Amended Complaint ("FAC") (ECF No. 17), which elaborated on Plaintiff's claims with respect to the presence of PFAS in the Product based upon TOF testing and the detrimental human health effects linked to PFAS, but did not include the recent direct PFAS test results because they were not yet available. Since the filing of the FAC, Plaintiff received the direct PFAS test results, which confirm the presence of several harmful PFAS compounds in the Product. Additionally, since the filing of the

FAC, the EPA made certain determinations regarding the toxicity of two of the specific PFAS compounds found in the Products. *See* Ex. 1 to the Richman Decl. at ¶¶ 23-26.

To the extent Plaintiff is required to show good cause to amend, he has done so. The recent test results affirmatively demonstrate that the Product contains specific PFAS compounds, and the recent EPA announcements lend further support for Plaintiff's allegations related to the harmful human health and environmental effects of these compounds. This information was not available to Plaintiff at the time of filing the initial complaint or FAC. The cases cited by Defendant on this point are inapposite. *See Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 340 (2d Cir. 2000) (plaintiff sought amendment after district court's deadline based upon language in a contract in plaintiff's possession prior to filing); *Kontarines v. Mortg. Elec. Registration Sys.*, No. 15-CV-2206 (ARR), 2016 U.S. Dist. LEXIS 90283, at *7-9 (E.D.N.Y. July 12, 2016) (plaintiff sought extension of deadline to amend his complaint after deadline had expired, discovery had already closed and "inordinate delay in this case," and failed to establish good cause); *State Trading Corp. v. Assuranceforeningen Skuld*, 921 F.2d 409, 412 (2d Cir. 1990) (court denied plaintiff's post-judgment motion to amend due to unjustified 19-month delay in seeking the amendment). *See also Palompelli v. Smith*, No. 20-CV-8070 (CS), 2022 U.S. Dist. LEXIS 37979, at *16-17 (S.D.N.Y. Mar. 3, 2022) (declining to grant leave to amend because plaintiff did not suggest that he is in possession of facts that would cure the deficiencies); *NCUA Bd. v. U.S. Bank Nat'l Ass'n*, 898 F.3d 243, 251 (2d Cir. 2018).

In fact, this Court has permitted plaintiffs to amend multiple times, even when, unlike here, discovery has already commenced or been completed. In *Clarke v. Antonini*, No. 21 Civ. 1877 (NSR), 2022 U.S. Dist. LEXIS 171707, at *36 (S.D.N.Y. Sep. 22, 2022), it was specifically noted that "while Plaintiff has already amended once, he claims to be in possession of facts that could

potentially cure the deficiencies that Defendants highlighted in their instant motions and that the Court highlighted in this opinion.” This is analogous to the case at hand, where Plaintiff is currently in possession of test results that cure all deficiencies noted in this Court’s Order. *See Megahey v. Cnty. of Westchester (In re D.J.)*, No. 14-cv-7635 (NSR), 2021 U.S. Dist. LEXIS 62958 (S.D.N.Y. Mar. 31, 2021) (granting leave for plaintiff to file Third Amended Complaint after commencement of discovery); *see also Crossborder Sols., Inc. v. Macias, Gini, & O’Connell, LLP*, 2022 U.S. Dist. LEXIS 31788 (S.D.N.Y. Feb. 23, 2022) (granting plaintiff’s request for leave to file Second Amended Complaint while discovery was ongoing).

Under Rule 15 of the Federal Rules of Civil Procedure, although a party that has already amended its pleadings may only amend again with “the opposing party’s written consent or the court’s leave,” the rule makes clear that leave to amend should be “freely give[n] when justice so requires.” Fed. R. Civ. P. 15(a)(2). Because the rule espouses a “policy in favor of granting leave to amend,” *Jaser v. N.Y. Prop. Ins. Underwriting Ass’n*, 815 F.2d 240, 243 (2d Cir. 1987), a court may generally only exercise its discretion “to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *Holmes v. Grubman*, 568 F.3d 329, 334 (2d Cir. 2009); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) (outlining circumstances where a motion to amend may be denied, including “undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of allowing the amendment, [or the] futility of amendment”).

III. PLAINTIFF’S AMENDMENTS ARE NOT FUTILE.

The recent test results establishing the presence of specific, harmful PFAS compounds in the Product directly address the deficiencies noted in this Court’s Order of dismissal and, along with the additional allegations related to harm and migration, cure the same.

First, Plaintiff adequately alleges in the SAC that he has suffered an injury-in-fact by purchasing a misbranded Product. Ex. 1 at ¶¶ 17, 18, 40-43, 47. The SAC alleges that the Product is made from ePTFE, explains that the manufacture of ePTFE requires the use of several hazardous PFAS (Ex.1 at ¶¶ 40-43, 165), and that the Products continue to be made from PTFE today (Ex. 1 at ¶ 42). In sum, Plaintiff sufficiently alleges in the SAC that PFAS compounds detected in Plaintiff's recent testing are the result of a main ingredient (itself, a PFAS) used by Defendant to create the Product – and that Defendant has neither substituted the main ingredient (ePTFE) nor changed the process by which the Product is manufactured since Plaintiff's purchases. This case is therefore distinguishable from those cited by Defendant, none of which involve products wherein a PFAS compound itself is the **main ingredient** of the product. *See Hernandez v. Wonderful Co. LLC*, No. 23-cv-1242 (ER), 2023 U.S. Dist. LEXIS 231476 (S.D.N.Y. Dec. 29, 2023) (pomegranate juice); *Onaka v. Shiseido Ams. Corp.*, No. 21-cv-10665-PAC, 2023 U.S. Dist. LEXIS 53220 (S.D.N.Y. Mar. 27, 2023) (cosmetics); *Esquibel v. Colgate-Palmolive Co.*, No. 23-CV-00742-LTS, 2023 U.S. Dist. LEXIS 201609 (S.D.N.Y. Nov. 9, 2023) (mouthwash). Here, Plaintiff has plausibly alleged that the presence of PFAS in the Products is “so widespread as to render it plausible that [Plaintiff] purchased a mislabeled Product at least once.” *Onaka*, 2023 U.S. Dist. LEXIS 53220, at *13 (also explaining that plaintiff, unlike here, had “provide[d] no facts from which the Court could extrapolate that their isolated testing should apply broadly to Defendant's Products, regardless of when they were purchased.”) In *Esquibel*, this Court explicitly noted that it “does not read *Onaka* as establishing a legal requirement that plaintiffs must test the specific units they purchased for PFAS in order to establish injury-in-fact. There are other ways plaintiffs could have established the plausibility of their injury. For example, “[by] rais[ing] a plausible inference that the Product was systemically contaminated such that any bottle of the

Product, including the ones plaintiffs purchased, likely contained PFAS.” 2023 U.S. Dist. LEXIS 201609, at *9. Here, Plaintiff has sufficiently alleged that the Product purchased by Plaintiff, and all Defendant’s Products, are contaminated with harmful PFAS because of the nature of the main ingredient and manufacturing process used.

Second, Plaintiff sufficiently alleges that the Products contain PFAS compounds that are harmful to human health, migrate into the user’s body and contribute to the user’s overall body burden of PFAS. Notably, in the Order, this Court explicitly took “judicial notice of the well-pled correlation between PFAS and adverse health effects” alleged in Plaintiff’s initial complaint. Order at p. 5. This Court determined, however, that because Plaintiff’s TOF testing could only establish the likely presence of PFAS, Plaintiff’s theory was missing a key link. This has been remedied through Plaintiff’s recent direct PFAS results establishing the presence of specific, harmful PFAS compounds in the Products.

In addition to detailed allegations relating to the mobile and bioaccumulative properties of PFAS in general, Plaintiff specifically alleges that “[u]pon information and belief, the PFAS within the Products migrate from the Product into the user’s body via oral absorption/ingestion and contribute to the user’s overall body burden of PFAS.” *See Ex. 1 at ¶ 119.* This is based upon the fact that consumers are directly, orally exposed to harmful PFAS via flossing with the Products. As explained, PFAS are mobile chemicals, accordingly dental floss such as Oral-B Glide sheds, and ingestion is a main pathway to PFAS exposure in humans. *See Ex. 1 at ¶ 94.*

Defendant’s attempt to compare Plaintiff’s direct PFAS results to the threshold level of 100 ppm of organic fluorine, widely used by the scientific community and state legislatures, as a screening tool for the presence of intentionally-added PFAS is nonsensical. It is unclear if Defendant is engaging in a transparent mischaracterization of Plaintiff’s results in an attempt to

downplay the results, or simply misunderstands the nature of PFAS testing on a fundamental level. Because TOF testing captures all compounds with carbon-fluorine bonds, the final result includes a complete quantification of the total amount of all PFAS present in the Product. In short, TOF testing screens the Product for all PFAS (even those for which no direct test is currently available) and gives an indication of the Product's overall PFAS load. In contrast, direct PFAS testing can identify the amounts of a handful of specific PFAS compounds for which testing is available. As such, direct PFAS results cannot be compared against the 100ppm threshold. Here, both the TOF and direct PFAS results when considered together, confirm that the Product has a shockingly high overall load of PFAS (***302,400 ppm*** or more than 3000 times the 100 ppm threshold level) as well as significant amounts of four specific harmful PFAS compounds. For context, while specific regulatory limits for the four PFAS identified in the SAC have not yet been established by Environmental Protection Agency (EPA), the EPA sets stringent limits on other PFAS compounds in water, often in the low parts per ***trillion*** (ppt) range.

Third, Defendant's argument that Plaintiff has not affirmatively established that the PFAS identified in the Product cause significant harm to human health is inappropriate for consideration on a motion to dismiss. Again, this Court has already taken judicial notice of the fact that PFAS negatively impact human health. Order at p. 5. Here, the relevant inquiry is whether a consumer would expect PFAS compounds to be present in an oral hygiene product that is marketed as "Pro-Health." Plaintiff has plausibly alleged in the SAC that the TOF and direct PFAS results read in conjunction with each other render Defendant's "Pro-Health" representation misleading.

Fourth, Defendant's "Pro-Health" and sustainability representations are not puffery. Defendant urges the Court to find that no reasonable consumer could possibly rely on its "Pro-Health" and environmental sustainability representations such as "environmental sustainability is

embedded in how we do business” (Ex. 1. At ¶ 67) –begging the question of why the company so pervasively uses the representations in its marketing. As set forth herein, the SAC alleges, in detail, both the particular statements at issue and the reasons why these are false as a reasonable consumer would interpret them. Defendant’s argument is essentially that the Court should stand in the shoes of the jury and make these fact determinations, which is improper. *See, e.g., Nasdaq Stock Mkt., Inc. v. Archipelago Holdings, LLC*, 336 F. Supp. 2d 294, 305 (S.D.N.Y. 2004) (Cote, J.) (A determination that promises directed to consumers are mere “puffery” is a question of fact that is generally left for the jury). *See, e.g., Bricklayers & Masons Local Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223, 244 (S.D.N.Y. 2012) (Swain, J.); *Colangelo v. Champion Petfoods USA, Inc.*, No. 6:18-CV-1228 (LEK/ML), 2020 U.S. Dist. LEXIS 26919, at *21 (N.D.N.Y. Feb. 18, 2020) (citing *Shema Kolainu-Hear Our Voices v. ProviderSoft, LLC*, 832 F. Supp. 2d 194, 209 (E.D.N.Y. 2010).)

Lastly, while the SAC references certain examples of PFAS contamination worldwide, it also sufficiently establishes that Defendant’s environmental sustainability representations are misleading to consumers. Again, the question is whether a reasonable consumer would expect a Defendant to be using harmful PFAS compounds, that persist and accumulate in the environment, in its manufacturing process while representing itself as an environmentally responsible company. The SAC adequately alleges that PFAS, in general, as well as the specific compounds identified in the SAC, have negative effects on the environment. *See* Ex. 1 at ¶¶ 5, 13, 37, 43-45, 59, 92, 100-105.

CONCLUSION

For the reasons set forth above, Plaintiff respectfully requests that the Court grant his Motion for Leave to File a Second Amended Complaint.

DATED: June 4, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 4, 2024, the foregoing document was served via ECF to all counsel of record, via electronic mail to the Court, and two courtesy copies were mailed to the Court.

By: /s/ Kim E. Richman
Kim E. Richman